Revised: July, 25, 2001

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K010586
1 of 3

510(k) Summary of Safety and Effectiveness

(according to document 807.92: Content and format of a 510 (k))

(1)
Submitter's name: Merck Biomaterial GmbH
Submitter's address: Frankfurter Str. 250, D-64271 Darmstadt, Germany, Tel.: +49-6151-723082
Contact person: Dr. Thomas Kiewitt/ Dr. Adelheid Liebendörfer
Date: xx February 2001

(2) Name of the device: Palamed®, PMMA bone cement

(3) Legally market device to which the submitter claims equivalence:
Palacos® PMMA bone cement, FDA no.: P 81002 D (1984)

(4) Description of Palamed®:
Palamed® is a fast setting polymer (polymethylmethacrylate) cement for use in bone surgery. Mixing of the two sterile components, consisting of a powder and a liquid, initially produces a paste, which is used to anchor the prosthesis to the bone or to fill an osseous defect. The hardened bone cement allows stable fixation of the prosthesis and transfers all stresses produced on movement to the bone via the large interface. Insoluble zirconium (IV) oxide is included in the cement powder as an x-ray contrast medium. The chlorophyll additive serves as optical marking of the bone cement at the site of the operation.

Material used:

The **powder component** is comprised of the following:

Polymethylacrylate, methylmethacrylate copolymer (Plex 6613): 79%
Polymethylacrylate, methylmethacrylate copolymer (Plex 6612): 8 %
Zirkoniumdioxide: 12 %
Benzoyl peroxide: 1 %
Chlorophyll VIII: 20 ppm

Methylmethacrylate-copolymer is the primary constituent of the powder component. Zirkoniumdioxide is added as a radiopacifier. Chlorophyll is added as a colorant to distinguish polymer from bone at the site of operation. Benzoylperoxide is the starter. All are typical components of bone cement.

The **liquid component (monomer)** is comprised of the following:

Methylmethacrylate: 98 %
N,N-Dimethyl-p-toluidine: 2 %
Chlorophyll: 21 ppm

Methylmethacrylatemonomer is the primary constituent of the liquid component. In much smaller quantities are the accelerator, N,N-dimethyl-p-toluidine, and the stabilizer, hydroquinone, both of which are typical constituents in PMMA bone cement.

Scientific concepts, significant physical and performance characteristics:

When the powder and liquid components are mixed, the accelerator speeds the generation of free radicals and the stabilizer in the liquid reacts with many of the early free radicals, but is soon consumed. Free radicals can then initiate formation of polymer chains.

Polymerization proceeds slowly over the first few minutes. Polymer chains at the surface of the powder beads mingle with monomer and newly formed polymer chains, while smaller beads may dissolve completely. The cement temperature rises as set-time of the cement approaches. Polymerization is essentially complete and the bone cement hardens within 15 minutes.

Palamed® is made of the same materials as the approved bone cements Palacos®R (P 810020) and Osteopal® (P810020/S4). These materials have shown to be biocompatible and have a long history of successful clinical use. Like in Palacos®R the copolymer powder is the combination of the two „Plexes" designated as 6613-F and 6612-F. Each plex is a specific copolymer of methyl methacrylate (MA). The only difference to Palacos®R is the slight variation in the ratio of the two Plexes.

By changing the ratio between the two plexes, Palamed® is slightly less viscous only in the mixing phase compared to Palacos®R.

The liquid monomer is identical and interchangeable between the cement systems.

Since Palamed® is substantially equivalent to Palacos®R (no chemical constituents added nor removed) no toxicological studies have been conducted.

(5) Statement of the intended use of the device:

Palamed® is indicated for use in arthroplastic procedures of the hip, knee and other joints for fixation of polymer or metallic prosthetic implants to living bone and revision of previous arthroplasty procedures.

(6)

Summary of the technological characteristics of the new device in comparison to those of the predicate device

The components of Palamed® are identical to the legally marketed device Palacos®R and are identically processed and sterilized. Merely the ratio of the prepolymerized PMMA-powders plex 6612 and 6613 are slightly different to achieve better handling characteristics during the cement application phase, i.e. reduced viscosity during the mixing phase.

The effectiveness and substantial equivalence of Palamed® was determined by in vitro mechanical comparative testing to Palacos®R and by comparing other relevant data. The results showed that Palamed® is at least equal to Palacos®R and thus fulfilled its intended use.
The non-clinical performance data (see chapter: „performance") comparing Palamed with the predicate device Palacos R confirm that in all relevant properties Palamed is at least as good as Palacos and that both bone cements are subatntially eqiuivalent.

In summary, Palamed® is safe and effective for use in the above mentioned indications. Palamed® is substantially equivalent to Palacos®R in all regards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 3 0 2001

Dr. Thomas Kiewitt
Merck Biomaterial GmbH
Frankfurter Str. 250
D-64271 Darmstadt
Germany

Re: K010586
Trade Name: Palamed® PMMA Bone Cement
Regulation Number: 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) Bone Cement
Regulatory Class: II
Product Code: LOD
Dated: July 30, 2001
Received: August 2, 2001

Dear Dr. Thomas Kiewitt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 010586

Device Name: Palamed®

Indications For Use:

Palamed® Bone Cement is indicated for use in arthroplastic procedures of the hip, knee and other joints for fixation of polymer or metallic prosthetic implants to living bone and revision of previous arthroplasty procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

for Mark N Milhauser

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010586